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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,525	07/28/2003	Peter Keeling	15056-4	4291

29137 7590 03/28/2005

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EXAMINER

LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/628,525	Applicant(s) KEELING ET AL.	
	Examiner Samuel W. Liu	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-17 is/are pending in the application.
- 4a) Of the above claim(s) 16 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-15 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

Claims 7-17 are pending.

Applicants' preliminary amendment filed 28 July 2003, which cancels claims 1-6 and 18-20, and amends claim 7, 14 and 17 has been entered. Thus, claims 7-17 are pending.

During a telephone conversation with Patricia A. McDaniels on March 9, 2005, a provisional election for polynucleotides was made to prosecute the provisionally elected Group I, claims 7-15. Affirmation of this election must be made by applicants in replying to this Office action. Claims 16 and 17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Applicants indicate that the election is made with traverse.

Therefore, elected claims 7-15 are under examination to the extent that they are drawn to the elected invention.

Objection to Specification/claim

The disclosure is objected to because of the following informalities:

The current the specification does not comply with one or more parts of 37 CFR 1.821-1.825 since on page 2, line 22, the specification recites amino acid sequence "AELSR", and on page 4, line 5, amino acid sequence "KXGGLGDV" without the requisite "SEQ ID NOs." for the indicated amino acid sequences. Correction is required. See also page 4, line 25, amino acid sequences "KTGGL" and ADPG". A new paper copy and a computer readable from (CRF) are required as is the statement regarding no new matter and that the paper and CRF copies are identical.

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On page 2, line 22, “SSTS” should be spelled out fully for the first instance of use: see also page 17, line 27, “TAC”; and page 18, line 10, “CAB”.

On page 9, line 19, the term “one-celled” appears to be awkward. Suggest “unicellular” instead.

In claim 7, suggested is change “a hybrid polypeptide” to “a fusion polypeptide” since in the item (b), claim 7 sets forth “...fused to”; and thus, use of the term “fusion” instead of “hybrid” would be consistent in the claims’ context thereof.

Appropriate correction is required.

IDS

The references cited in the information disclosure statements (IDS) submitted 14 June 2004 have been placed in the file. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Claim Rejections - 35 USC § 112, the second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 7-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites “a starch-encapsulating region” since the specification does not provide the clear-cut definition for this recitation, one skilled in the art would not clearly know what is

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the structural characteristics of the said region; e.g., the starch-encapsulating region in starch synthase or starch branching enzyme or granule bound starch synthase (see page 8, the 3rd paragraph). Thus, the recitation is considered to be indefinite. The description or/and the corresponding sequence of said region is required thereof. The dependent claims (claims 8-12 and 13-14) are also rejected.

Claim 12 is indefinite because the claim is directed to a control element for expressing the starch-encapsulating region which is unclearly set forth in claims 7 and 9 from which claim 12 depends (see the above statement).

Claim 14 recites "A cell transformed to comprises..."; the recitation is not apparent as to whether or not the said cell is transformed with the expression vector comprising the recombinant nucleic acid molecule or directly transformed with said molecule.

Claim Rejections - 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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The claims 7, 9 and 13-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Villand, P. et al. (US Pat. No. 5977437).

In Example 8, Villand et al. teach a recombinant polynucleotide comprising starch branching enzyme (75 amino acids) and a biologically active polypeptide ADP glucose prophosphorylase (AGP). Because the specification sets forth that any starch branching enzyme has the starch-encapsulating region (page 8, the 3rd paragraph) whereas the specification does not make it clear as to what is structure of said region in the enzyme (see the rejection under 35 USC, second paragraph), and because the specification sets forth that payload polypeptide includes any bioactive polypeptide (see page 8, lines 6-7), the above Villand's teaching anticipates the instant claim 7.

On column 11, lines 48-54, Villand et al. teach that the host cell for expression of the polynucleotide is plant cell, the above Villand's teaching anticipates the instant claim 9. In Example 8, the said polynucleotide is cloned in an expression vector (e.g., pPPL5), which anticipates the instant claim 13.

In Example 9, Villand et al. teach a cell transformed with the recombinant polynucleotide, which anticipates the instant claim 14.

In abstract and the patent claims 11-16, the Villand's patent sets forth a (transgenic) plant transformed with the recombinant polynucleotide. Thus, the above-mentioned cell is a plant cell, which anticipates the instant claim 15.

The claims 7-9 and 13-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Block M. et al. et al. (US Pat. No. 6307125).

In Example 7, Block et al. teach a recombinant polynucleotide comprising a fusion polypeptide that comprises a fragment (cDNA) of alpha-peptide of the β -galactosidase and a part of the soluble starch synthase. Because the specification sets forth that any starch branching enzyme has the starch-encapsulating region (page 8, the 3rd paragraph) whereas the specification does not make it clear as to what is structure of said region in the enzyme (see the rejection under 35 USC, second paragraph), and because the specification sets forth that payload polypeptide includes any bioactive polypeptide (see page 8, lines 6-7), the above Block's teaching anticipates the instant claim 7.

In Example 7, Block teach an *E.coli* strain transformed with the recombinant polynucleotide, which anticipates the instant claim 8.

In Example 7, Block et al. teach that the said polynucleotide is cloned in an expression vector (e.g., pTaSSS Δ 188), which anticipates the instant claim 13.

In Example 7, Block et al. teach that cell (the above-mentioned *E.coli* transformant) which is transformed with the vector pTaSSS Δ 188, which anticipates the instant claim 14.

In the patent claim 15, Block et al. teach an isolated nucleic acid molecule comprising a nucleotide sequence encoding a protein of a starch synthase activity, wherein said synthase has the starch-encapsulating region (see the above); in the patent claims 17-18 and 20, Block further teach a plant cell transformed with an expression vector comprising the nucleic acid molecule. The Block' teachings thus anticipate the instant claims 7, 9 and 14-15.

Claim Rejections - 35 USC §103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Block M. et al. et al. (US Pat. No. 6307125).

In Example 7, Block et al. teach a recombinant polynucleotide comprising a fusion polypeptide that comprises a fragment (cDNA) of alpha-peptide of the β -galactosidase and a part of the soluble starch synthase. Because the specification sets forth that any starch branching enzyme has the starch-encapsulating region (page 8, the 3rd paragraph) whereas the specification does not make it clear as to what is structure of said region in the enzyme (see the rejection under 35 USC, second paragraph), and because the specification sets forth that payload polypeptide includes any bioactive polypeptide (see page 8, lines 6-7), the above Block's teaching is applied to the instant claim 7.

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On column 7, lines 31-43, Block et al. teach the host cell for transformation with the polynucleotide is a plant cell, as applied to the instant claim 9.

On column 7, lines 31-43, Block et al. further teach that said plant cell is either monocotyledonous (i.e., monocot), as applied to the instant claim 10; or, dicotyledonous (i.e., dicot), as applied to the instant claim 11.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to chose the monocotyledonous or dicotyledonous plant cell for transformation with the claimed polynucleotide in the Block' patent. One skilled in the art would have been motivated to do this because, although in the claims and Examples sections the patent does not disclose the plant cells thereof, Block et al. does teach that the monocotyledonous or dicotyledonous plant cell is particular useful as they are starch-synthesizing or starch-storing plants (see column 7, lines 37-40), and because, on columns 9-12, Block's patent also discusses usefulness of the starch polymer produced by these plant cells, e.g., in foodstuffs, paper and cardboard industry and Textile industry (see column 10, the right column). Therefore, the claimed invention was *prima facie* obvious to make and use the invention at the time it was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber, Jon, can be

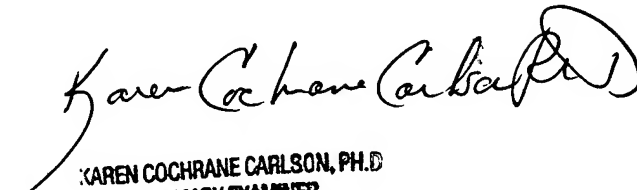
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reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

SNL

Samuel Wei Liu, Ph.D.
Art Unit 1653, Examiner
March 15, 2005


KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER